



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,671	11/28/2001	Arthur L. Vellutato	100858.00106	1544

27557 7590 09/11/2002

BLANK ROME COMISKY & MCCUALEY, LLP
900 17TH STREET, N.W., SUITE 1000
WASHINGTON, DC 20006

[REDACTED] EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
1744	[REDACTED]

DATE MAILED: 09/11/2002

[Signature]

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/994,671	Applicant(s)	VELLUTATO, ARTHUR L. <i>AM</i>
Examiner	Leigh McKane	Art Unit	
		1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 May 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 28 November 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1, "said irradiating step" lacks positive antecedent basis as claim 3 fails to recite an "irradiating step".

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Clean Rooms Magazine* (Reader Service No. 498) in view of Perlman (U.S. Patent No. 5,060,823).

The excerpt from *Clean Rooms Magazine* teaches that it was known in the art at the time the invention was made to package an alcohol solution in an aerosol container (which by definition is pressurized), double bag the container in a sterile pack (e.g. hermetically sealed), and terminally sterilize the resulting pack. Since the double bag forms a "sterile pack," it is necessarily hermetically sealed. The excerpt from *Clean Rooms Magazine* does not teach that an inert gas is used to pressurize the aerosol container or to using radiation for the terminal sterilization.

Perlman discloses a method whereby a solution is packaged within an aerosol container with a nitrogen gas propellant, sealed, and irradiated with gamma radiation to sterilize the entire assembly. See Example 1. It would have been obvious to one of ordinary skill in the art to package the alcohol solution of *Clean Rooms Magazine* with nitrogen gas as Perlman teaches that nitrogen reduces the rate of oxidation or chemical decomposition of the solution. Moreover, it acts as a propellant of the aerosol solution. See col.2, lines 62-65. Furthermore, one would have found it obvious to use gamma radiation as the means by which to terminally sterilize the product of *Clean Rooms Magazine*, since Perlman evidences that gamma radiation is effective in terminal sterilization of aerosol solutions.

The disclosure of *Clean Rooms Magazine* does not indicate the type of material from which the aerosol container is made. Perlman teaches that aerosol containers are commonly made from rigid materials such as metal, glass, or plastic. See col.2, lines 29-30. Given this evidence, it would have been obvious to one of ordinary skill in the art to choose a suitable material for the container.

Art Unit: 1744

6. Claims 3, 4, 8, and 19- 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falciani et al (U.S. Patent No. 4,700,838) in view of Anthony et al (U.S. Patent No. 4,714,595).

With respect to claims 3, 19, and 22, Falciani et al teaches storing a chemical composition within a sealed container 1. This sealed container is hermetically sealed within first 2 and second 3 hermetically sealed containers, and a shipping enclosure (corrugated cardboard box). Falciani et al teaches that the container 1 can be removed from the outer containers without compromising the sterility of the chemical composition. Although Falciani et al does not specify heat sealing the bags, one of ordinary skill in the art would have been aware of appropriate means by which to seal plastic bags.

Similarly, Anthony et al discloses sealing layers for storage wherein the interior container can be maintained in a sterile state even in a non-sterile environment. Thereafter, a first sealed container is removed from a second sealed container in the non-sterile environment and transferred to the sterile environment. See col.4, lines 1-14. In addition, Anthony discloses the terminal gamma sterilization of a multilayered package assembly. As such assures the sterility of all layers of packaging, it would have been obvious to apply to the method of Falciani et al. Moreover, in using the system of Falciani et al it would have been obvious that some time in transport the containers would be removed from the shipping enclosure and stored for a period of time, even if only for a period of minutes. From ~~the~~ ^{that} point, each successive enclosure would be removed, leaving the resulting container in a storage ~~area~~ ^{area} for a period of time.

As to claim 4, it would have been obvious to apply the method of Falciani et al to a sterile environment, as the pharmaceutical products packaged and sterilized by Falciani et al are often tested and evaluated in sterile environments.

With respect to claim 8, Falciani et al teaches that the first sealing enclosure is formed of polyethylene and the second sealing enclosure is a laminate of polyethylene, aluminum foil, and polyester resin. However, it is not considered inventive to use the same material for both layers as such would have increased the economy of production.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Falciani et al and Anthony et al as applied to claim 3 above, and further in view of *Clean Rooms Magazine* (Reader Service No. 498) and Anderson (U.S. Patent No. 4,896,768).

Falciani et al does not specify that isopropyl alcohol is the chemical or pharmaceutical that is packaged and sterilized within the container system. The excerpt from *Clean Rooms Magazine* teaches that it was known in the art at the time the invention was made to package an alcohol solution in an aerosol container (which by definition is pressurized), double bag the container in a sterile pack (e.g. hermetically sealed), and terminally sterilize the resulting pack. Thus, it would have been obvious to use the method of Falciani et al to package and sterilize isopropyl alcohol. Note that Falciani et al specifically teaches that the container system can be used for sterile liquids (col.2, line 31). Although Falciani et al teaches sterilizing with gamma rays (col.2, lines 43), a dose is not disclosed. Anderson discloses terminally sterilizing liquid chemicals with a dose of 0.05-2.0 Mrad (5-200 kGy). See col.4, lines 1-9. As sterilization dose is a result effective variable, it would have been obvious to one of ordinary skill in the art to optimize the dose of radiation applied according to the particular chemical composition and the contamination present.

Art Unit: 1744

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Falciani et al and Anthony et al as applied to claim 3 above, and further in view of Perlman.

Falciani et al does not disclose that the sealed container 1 has a cap closure. However, Perlman teaches terminally sterilizing a chemical composition contained with a pressurized container 12 with a cap 22. It is deemed obvious to substitute the container of Perlman for that of Falciani et al, as the container of Perlman is well-known in the art for holding liquids.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Falciani et al and Anthony et al as applied to claim 3 above, and further in view of *Clean Rooms Magazine* (Reader Service No. 498).

Falciani et al does not specify that isopropyl alcohol is the chemical or pharmaceutical that is packaged and sterilized within the container system. The excerpt from *Clean Rooms Magazine* teaches that it was known in the art at the time the invention was made to package an alcohol solution in an aerosol container (which by definition is pressurized), double bag the container in a sterile pack (e.g. hermetically sealed), and terminally sterilize the resulting pack. Thus, it would have been obvious to use the method of Falciani et al to package and sterilize isopropyl alcohol. Note that Falciani et al specifically teaches that the container system can be used for sterile liquids (col.2, line 31).

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Falciani et al and Anthony et al as applied to claim 3 above, and further in view of Anderson.

Although Falciani et al teaches sterilizing with gamma rays (col.2, lines 43), a dose is not disclosed. Anderson discloses terminally sterilizing liquid chemicals with a dose of 0.05-2.0 Mrad (5-200 kGy). See col.4, lines 1-9. As sterilization dose is a result effective variable, it

Art Unit: 1744

would have been obvious to one of ordinary skill in the art to optimize the dose of radiation applied according to the particular chemical composition and the contamination present.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Falciani et al and Anthony et al as applied to claim 3 above, and further in view of *Clean Rooms Magazine* (Reader Service No. 498) and Perlman.

Falciani et al teaches that a liquid may be within the container 1, but does not disclose an aerosol container pressurized with an inert gas. The excerpt from *Clean Rooms Magazine* teaches that it was known in the art at the time the invention was made to package an liquid solution in an aerosol container (which by definition is pressurized), double bag the container in a sterile pack (e.g. hermetically sealed), and terminally sterilize the resulting pack. Therefore, it would have been obvious to use the method of Falciani et al to package and sterilize an aerosol container since aerosol containers are known to contain liquids and are capable of being packaged and terminally sterilized. Moreover, it would have been obvious to one of ordinary skill in the art to package the solution with nitrogen gas as Perlman teaches that nitrogen reduces the rate of oxidation or chemical decomposition of the solution. Moreover, it acts as a propellant of the aerosol solution. See col.2, lines 62-65.

12. Claims 11-14, 17, 18, and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Clean Rooms Magazine* in view of Perlman, Falciani et al, and Anthony.

The excerpt from *Clean Rooms Magazine* teaches that it was known in the art at the time the invention was made to package an alcohol solution in an aerosol container (which by definition is pressurized), double bag the container in a sterile pack (e.g. hermetically sealed), and terminally sterilize the resulting pack. Since the double bag forms a "sterile pack," it is

Art Unit: 1744

necessarily hermetically sealed. The excerpt from *Clean Rooms Magazine* does not teach that an inert gas is used to pressurize the aerosol container, enclosing the double bagged container within a shipping container, or using radiation for the terminal sterilization of the entire assembly.

Perlman discloses a method whereby a solution is packaged within an aerosol container with a nitrogen gas propellant, sealed, and irradiated with gamma radiation to sterilize the entire assembly. See Example 1. It would have been obvious to one of ordinary skill in the art to package the alcohol solution of *Clean Rooms Magazine* with nitrogen gas as Perlman teaches that nitrogen reduces the rate of oxidation or chemical decomposition of the solution. Moreover, it acts as a propellant of the aerosol solution. See col.2, lines 62-65.

Falciani et al teaches storing a chemical composition within a sealed container 1. This sealed container is hermetically sealed within first 2 and second 3 hermetically sealed containers, and a shipping enclosure (corrugated cardboard box). As a shipping container would have been necessary for the transportation of the "sterile pack" of *Clean Rooms Magazine*, it would have been obviously used therein.

Anthony discloses the terminal gamma sterilization of a multilayered polyethylene package assembly. As such assures the sterility of all layers of packaging, it would have been obvious to apply to the combination of *Clean Rooms Magazine* with Perlman and Falciani et al.

In addition, it would have been obvious to fabricate the double bags of *Clean Rooms Magazine* from a suitable material, such as the polyethylene of Anthony et al.

Art Unit: 1744

13. Claims 15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Clean Rooms Magazine* in view of Perlman, Falciani et al, and Anthony as applied to claims 11 and 23 above, and further in view of Anderson.

The combination *supra* teaches the use of gamma radiation for terminally sterilizing packages but a dose is not disclosed. Anderson discloses terminally sterilizing liquid chemicals with a dose of 0.05-2.0 Mrad (5-200 kGy). See col.4, lines 1-9. As sterilization dose is a result effective variable, it would have been obvious to one of ordinary skill in the art to optimize the dose of radiation applied according to the particular chemical composition and the contamination present.

14. Claims 16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Clean Rooms Magazine* in view of Perlman, Falciani et al, Anthony, and Anderson as applied to claims 15 and 27 above, and further in view of Pomerantz et al (U.S. Patent No. 2,904,392).

Although the above combination teaches the application of gamma radiation to a package for terminal sterilization, it is not disclosed to apply the gamma radiation in a plurality of directions. Pomerantz et al teaches that containers are sterilized by exposing "each side" of the article to irradiation. See col.4, line 7. One would have found it obvious to irradiate all sides if the container being sterilized in order to assure complete sterilization.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

Art Unit: 1744

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Leigh McKane
Leigh McKane
Primary Examiner
Art Unit 1744

elm
September 9, 2002